UNITED STATES DISTRICT COURT
For the
SOUTHERN DISTRICT OF ILLINOIS
EAST ST. LOUIS DIVISION

C.M., a minor, by and through DENISE MILAM, individually and as next friend of C.M.; T.D., a minor, by and through MARY DANIELS, individually and as next friend of T.D.; A.C., a minor, by and through STACY CLEMONS, individually and as next friend of A.C.; K.H., a minor, by and through, KRISTIN WIGGINS, individually and as next friend of K.H.; H.M., a minor, by and through KAYLEE MARSHALL, individually and as next friend of H.M.; C.M., a minor, by and through MARICELA MARTINEZ, individually and as next friend of C.M.; K.U., a minor, by and through CHRISTY UZZELL, individually and as next friend of K.U.; T.K., a minor, by and through KRISTINA KAPP, individually and as next friend of T.K.;	)	Case No. 3:14-cv-00001-JPG-PMF
Plaintiffs,	)	
v.	)	
ABBOTT LABORATORIES, INC.,	)	
Defendant.	)	

PLAINTIFFS' COMPLAINT

Come now PLAINTIFFS, individuals, and minors by their respective parent(s) and next friend of Plaintiffs, by and through their undersigned attorneys, for their Complaint against Defendant Abbott Laboratories, Inc. (hereinafter "Abbott" or "Defendant") relative to its sale

and distribution and manufacturing of the drug Depakote and Depakote ER products (hereinafter "Depakote") in the United States, and in support thereof would show the following:

PARTIES AND JURISDICTION

Plaintiffs

1. Plaintiffs C.M., a minor, by Denise Milam, individually as parent and next friend of C.M., are citizens and residents of Montgomery, Alabama. Plaintiff C.M. was born in 2002. Her injuries were caused by her mother's ingestion of Depakote during pregnancy, and specifically, during her first trimester of pregnancy. Plaintiff C.M. avers that Defendant's Depakote was defectively designed, inadequately tested, dangerous to human health and unborn, and lacked proper warnings as to the true danger associated with its use, and Plaintiffs suffered injury as a result of the mother's ingestion of Depakote.

2. Plaintiffs T.D., a minor, by Mary Daniels, individually as parent and next friend of T.D., are citizens and residents of Livingston, Alabama. Plaintiff T.D. was born in 1996. Her injuries were caused by her mother's ingestion of Depakote during pregnancy, and specifically, during her first trimester of pregnancy. Plaintiff T.D. avers that Defendant's Depakote was defectively designed, inadequately tested, dangerous to human health and unborn, and lacked proper warnings as to the true danger associated with its use, and Plaintiffs suffered injury as a result of the mother's ingestion of Depakote.

3. Plaintiffs A.C., a minor, by Stacy Clemmons, individually as parent and next friend of A.C., are citizens and residents of Rockford, Illinois. Plaintiff A.C. was born in 2002. Her injuries were caused by her mother's ingestion of Depakote during pregnancy, and

specifically, during her first trimester of pregnancy. Plaintiff A.C. avers that Defendant's Depakote was defectively designed, inadequately tested, dangerous to human health and unborn, and lacked proper warnings as to the true danger associated with its use, and Plaintiffs suffered injury as a result of the mother's ingestion of Depakote.

4. Plaintiffs K.H., a minor, by Kristin Higgins, individually as parent and next friend of K.H., are citizens and residents of Winchendon, Massachusetts. Plaintiff K.H. was born in 2007. Her injuries were caused by her mother's ingestion of Depakote during pregnancy, and specifically, during her first trimester of pregnancy. Plaintiff K.H. avers that Defendant's Depakote was defectively designed, inadequately tested, dangerous to human health and unborn, and lacked proper warnings as to the true danger associated with its use, and Plaintiffs suffered injury as a result of the mother's ingestion of Depakote.

5. Plaintiffs H.M., a minor, by Kaylee Marshall, individually as parent and next friend of H.M., are citizens and residents of Atkins, Arkansas. Plaintiff H.M. was born in 2010. His injuries were caused by his mother's ingestion of Depakote during pregnancy, and specifically, during her first trimester of pregnancy. Plaintiff H.M. avers that Defendant's Depakote was defectively designed, inadequately tested, dangerous to human health and unborn, and lacked proper warnings as to the true danger associated with its use, and Plaintiffs suffered injury as a result of the mother's ingestion of Depakote.

6. Plaintiffs C.M., a minor, by Maricela Martinez, individually as parent and next friend of C.M., are citizens and residents of Fontana, California. Plaintiff C.M. was born in 1997. His injuries were caused by his mother's ingestion of Depakote during pregnancy, and specifically, during her first trimester of pregnancy. Plaintiff C.M. avers that Defendant's Depakote was defectively designed, inadequately tested, dangerous to human health and unborn,

and lacked proper warnings as to the true danger associated with its use, and Plaintiffs suffered injury as a result of the mother's ingestion of Depakote.

7. Plaintiffs K.U., a minor, by Christy Uzzell, individually as parent and next friend of K.U., are citizens and residents of Springhill, Tennessee. Plaintiff K.U. was born in 2003. Her injuries were caused by her mother's ingestion of Depakote during pregnancy, and specifically, during her first trimester of pregnancy. Plaintiff K.U. avers that Defendant's Depakote was defectively designed, inadequately tested, dangerous to human health and unborn, and lacked proper warnings as to the true danger associated with its use, and Plaintiffs suffered injury as a result of the mother's ingestion of Depakote.

8. Plaintiffs T.K., a minor, by Kristina Kapp, individually as parent and next friend of T.K., are citizens and residents of Spanish Fort, Alabama. Plaintiff T.K. was born in 2003. Her injuries were caused by her mother's ingestion of Depakote during pregnancy, and specifically, during her first trimester of pregnancy. Plaintiff T.K. avers that Defendant's Depakote was defectively designed, inadequately tested, dangerous to human health and unborn, and lacked proper warnings as to the true danger associated with its use, and Plaintiffs suffered injury as a result of the mother's ingestion of Depakote.

Defendant

9. Defendant Abbott Laboratories, Inc. now is, and at all times relevant to this action was, a corporation organized and existing under the laws of the State of Illinois, with its principal place of business and its headquarters in the State of Illinois. Abbott may be served by delivering the citation to its registered agent for service, CT Corporation System, 208 So. LaSalle St., Suite 814, Chicago, IL, 60604.

10. Abbott engaged in the business of designing, licensing, manufacturing, testing, advertising, warranting, distributing, supplying, selling, and introducing into the stream of commerce certain products known as Depakote and Depakote ER. Abbott sold and marketed its Depakote and Depakote ER products in this District and throughout the United States.

JURISDICTION AND VENUE

11. This court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332. Defendant is resident of the state of Illinois, there is complete diversity of citizenship between all Plaintiffs and the Defendant, and the amount in controversy exceeds $75,000.00.

12. Venue is proper in this district under 28 U.S.C. § 1391(b)(1) and 1391(d) due to Defendant's substantial contacts to this district, including direct-to-consumer marketing, communication with and marketing to physicians, and the sale of Depakote and other pharmaceutical products in this district.

13. This lawsuit seeks compensation, damages and other relief for injuries Plaintiffs have suffered as a result of Abbott's anti-convulsant drug commonly known as "Depakote." Plaintiffs herein are properly joined pursuant to Fed. R. Civ. P. 20(a)(1). As detailed in this complaint, Plaintiffs' claims and rights of relief arise out of the same series of transactions and occurrences, including but not limited to, the Defendant's creating, developing, researching, studying, testing, licensing, manufacturing, promoting, advertising, warranting, marketing, selling, and distributing the drug Depakote. Furthermore, as alleged in this complaint, the Plaintiffs' claims and right to relief, if brought separately, present common questions of law or fact, including what information Abbott possessed concerning the harmful effects of Depakote,

what information it elected to disclose to physicians and patients about these harmful effects, and what information they were required by law to disclose about those effects.

UNDERLYING COMMON FACTS

14. Abbott is and at all relevant times has been engaged in the business of formulating, designing, manufacturing, licensing, testing, advertising, marketing, warranting, selling, distributing, and introducing into the stream of commerce a drug compound known as "divalproex sodium," "valpronic acid," or "valproate," which Abbott has sometimes marketing under brand names such as "Depakote," "Depakote ER," "Depakene," and "Depacon." Regardless of the name under which Abbott marketed, sold, and distributed the drug, all of its forms were and are, for all purposes relevant to Plaintiffs' claims, chemically and pharmacologically identical. For purposes of this complaint, these various forms and names of the drug compound will all be referred to by the common brand name, "Depakote."

15. In 1978, after Abbott received approval to market Depakote in the United States for treatment of certain forms of epilepsy, Abbott began marketing and placing Depakote into the stream of commerce throughout the United States. Depakote was promoted as an effective anti-epileptic drug ("AED").

16. Depakote was formulated, designed, manufactured, licensed, tested, advertised, marketed, warranted, sold, distributed, and introduced into the stream of commerce by Abbott, was and is defective and unreasonably dangerous for its intended use. In particular, the primary compound in Depakote—valproic acid—has been known to cause severe birth defects if taken during the first trimester of pregnancy.

17. Among the "major congenital anomalies" (i.e., birth defects) known to result directly from first-trimester exposure to Depakote are, either singly or in some combination with each other, spina bifida, cleft palate, cleft lip, limb and digital deformities, facial dysmorphism, mental developmental delays, genitourinary malformations, and heart defects.

18. Medical researchers have confirmed that while Depakote is effective at controlling seizures, it is also riskier than other modern AEDs for women who are pregnant or may become pregnant.

19. Abbott has been aware of the birth defects associate with Depakote on early-term pregnancies on or before the date it began marketing and distributing Depakote in the United States.

20. Scientific articles single out Depakote as among the most—if not the most—teratogenic of all AEDs. One study in 1995 reported an incidence rate of neural tube defects (such as spina bifida) *ten times greater* than with other AEDs. Another study found major congenital abnormalities in eleven percent of all infants exposed to Depakote during the earliest weeks of pregnancy.

21. As pharmaceutical research and development progressed through the 1980's and 1990's, new and better AEDs were developed and approved, which proved as effective as Depakote at controlling most seizures in most epileptic patents, but which bore far less risk of causing birth defects.

22. Despite this emerging scientific consensus, Abbott refused to communicate the true nature and extent of the risk in its product labeling and warnings to physicians and consumers.

23. Instead of working to warn doctors and women of childbearing age about the sharply heightened risks involved with ingesting Depakote during the early weeks of pregnancy, Abbott has sought to minimize the risks and downplay the dangers in its product labeling of Depakote.

24. Despite the risks of major congenital malformations, Abbott has aggressively pursued expansion of the uses for which Depakote is approved and marketed to doctors and patients. As early as the mid-1990's, Abbott implicitly and explicitly promoted Depakote to doctors, consumers, and the general public for unapproved or "off-label" uses, such as for treatment of mild depression, the depressive state of bi-polar disorder, and chronic pain such as migraine headaches.

25. Abbott has promoted these off-label uses even though there are other common drugs which are as effective or more effective for treatment of those conditions, and which do not involve the severe risk of congenital malformations associated with Depakote. In further pursuit of market share in the pharmaceutical industry, Abbott has worked aggressively to manipulate the regulatory system and gain approval for certain of these off-label uses, in hopes of concealing within government approval the dangers of using Depakote for conditions in which its use is unnecessary.

26. Abbott has concealed risks from and otherwise misled doctors who prescribe Depakote and monitor patients' drug regimen during pregnancy. Despite knowing the extremely high incidence rate of major congenital malformations in babies born to women who take Depakote while pregnant (one study suggested a risk of up to *one in every five pregnancies*, while others have found the risk is at least one in ten), Abbott continues to downplay the risks and refuses to provide adequate information in the Depakote label and package inserts regarding

the true scope and severity of the dangers. Instead, Abbott insists on using muted and understated language to suggest that women of childbearing age weigh the "potential risks," when in fact the risks are severe, well-known to Abbott, and in scientific reality in excess of the injuries and incident rates reported in the label.

27. The most tragic aspect of the inadequate label is that Depakote causes irreversible and devastating injuries to the developing child *before the mother or the physician even have a chance to discover the pregnancy*. Abbott knew or should have known it had a duty to warn doctors and patients that women who were taking Depakote should not get pregnant, and that women who might become pregnant should not take Depakote. This simple warning, commonplace with countless pharmaceuticals, would have spared each Plaintiff a lifetime of pain and suffering, inordinate healthcare costs, several emotional and physical distress, and loss of earning potential.

28. Depakote was and is a defective product, unreasonably dangerous in light of its nature and intended use. The defect existed when the product left Abbott's control and has been the proximate cause of injuries to Plaintiffs, whose injuries were caused by the use of Depakote in its intended or foreseeable manner or in the manner recommended by Abbott.

29. Abbott knew or should have known of the dangerous condition of its product, Depakote, but failed to adequately warn or instruct physicians and consumers of the risks, dangers, and proper uses of the drug.

30. Abbott has breached its duty of reasonable care and its express and implied warranties, and has made affirmative misrepresentations as well as misrepresentations by omission, all in connection with the design, testing, manufacture, marketing, and/or labeling of Depakote.

31. As a direct and proximate result of the acts and omissions of Defendant, the Injured Children, such as Plaintiffs, were born with spina bifida, heart defects and neural tube defects, among other congenital malformations and birth defects. The Injured Children continue to suffer permanent injury, pain, loss of normal life, and other non-economic damages.

32. As a direct and proximate result of the aforesaid acts of and/or omissions by the Defendant, the Injured Children have:

(a) suffered severe and permanent injuries, which they will be forced to endure for the remainder of their lives;

(b) suffered physical impairment and disfigurement;

(c) suffered physical pain and suffering;

(d) suffered mental pain and suffering;

(e) suffered loss of enjoyment of life;

(f) incurred substantial costs for medical care in the past, and will, in reasonable medical probability, incur substantial costs for medical care in the future;

(g) suffered a loss of earnings and of future earning capacity; and,

(h) incurred attorney's fees and expenses of litigation related to this action.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

33. Defendant failed to disclose a known defect and affirmatively misrepresented that Depakote was safe for its intended use. Further, Defendant actively concealed the true risks associated with the use of Depakote. Plaintiffs, the parents of the Injured Children, and/or the prescribing physicians had no knowledge that Defendant was engaged in the wrongdoing alleged herein. Because of Defendant's concealment of and misrepresentations regarding the true risks associated with Depakote, Plaintiffs, the parents of the Injured Children, and/or the prescribing

physicians could not have reasonably discovered Defendant's wrongdoing at any time prior to the commencement of this action.

34. Thus, because Defendant fraudulently concealed the defective nature of Depakote and the risks associated with its use, the running of any statute of limitations has been tolled. Likewise, Defendant is estopped from relying on any statute of limitations.

COUNT I

Strict Products Liability

35. Plaintiffs incorporate the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

36. It was the duty of Abbott to manufacture, test, market, advertise, label, distribute, and sell Depakote so that it was reasonably safe for its foreseeable use.

37. At the time Depakote left the control of Abbott and was sold, it contained one or more conditions, which rendered it defective and unreasonably dangerous in light of its nature and intended use.

38. At all times, Depakote was used in the manner intended, recommended, or reasonably foreseeable by Abbott. There were and are no other reasonable, secondary causes of Plaintiffs' injuries and damages other than the use of Depakote.

39. The Depakote manufactured and/or supplied by Abbott and to which Plaintiffs were exposed was defective in design, manufacture, and/or formulation in that when it left the hands of Abbott, the foreseeable risks exceeded the benefits associated with the design and/or formulation of this product.

40. The Depakote marketed, sold, and supplied by Abbott and to which Plaintiffs were exposed was defective in its marketing and labeling in that Abbott knew or should have known of its dangers and risks when taken during the first trimester of pregnancy, but failed to adequately warn or instruct physicians, consumers, and the general public of the nature and extent of those risks.

41. The Depakote marketed, sold, and supplied by Abbott and to which Plaintiffs were exposed was defective in its marketing and labeling in that Abbott knew or should have known of its dangers and risks when taken during the first trimester of pregnancy, as well as the means for reducing or eliminating those dangers and risks, but failed to adequately warn or instruct physicians, consumers, and the general public of those means of reducing or eliminating the risks.

42. The Depakote marketed, sold, and supplied by Abbott was defective in marketing in that Abbott represented to the consuming public that the product was safe and had qualities that it, in fact, did not have.

43. The Depakote manufactured and/or supplied by Abbott was defective in design and formulation in that it was more dangerous than an ordinary consumer would expect when used in its intended or reasonably foreseeable manner.

44. The Depakote manufactured and/or distributed by Abbott was defective in that Abbott failed to adequately test this product before placing it into the stream of commerce.

45. As a direct and proximate result of the defective condition of Depakote as manufactured by Abbott, Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

COUNT II

Negligence

46. Plaintiffs incorporate the allegations contained in the foregoing paragraph as if fully set forth in the following paragraphs.

47. Abbott had a duty to exercise reasonable care in the design, manufacture, testing, sale, labeling and/or distribution of Depakote it placed into the stream of commerce, including a duty to assure that the product did not cause unreasonable or unnecessary injury.

48. Abbott breached its duty of care to the Plaintiffs through its negligent acts and omissions. Abbott did not exercise reasonable care in the warning, design, manufacture, sale, testing, labeling and/or distribution into the stream of commerce of the Depakote in that Abbott knew or should have known that Depakote could cause serious birth defects if taken by pregnant women.

49. Abbott was negligent in the design, manufacture, sale, testing and/or distribution of Depakote in that it: (1) failed to use due care in designing, formulating, developing, testing, and manufacturing Depakote so as to avoid or warn against the described risks to consumers who used Depakote; (b) placed an unsafe product into the stream of commerce; and (c) failed to discover or warn of the dangers associated with the use of Depakote despite having actual and/or constructive knowledge of such dangers.

50. Abbott knew or should have known that Plaintiffs could foreseeably suffer injuries as a result of Abbott's failure to exercise ordinary care as described above.

51. As a direct and proximate result of Abbott's negligence, Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

COUNT III

Gross Negligence

52. Plaintiffs incorporate the allegations contained in the foregoing paragraph as if fully set forth in the following paragraphs.

53. Each of the foregoing acts or omissions by Abbott, when viewed objectively from their standpoint at the time, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to the Plaintiffs and others.

54. Abbott acted with conscious disregard for the rights, safety, or welfare of Plaintiffs and others. Their deceptive and inadequate labeling and marketing, misrepresentation of the risks of Depakote to doctors and women of child-bearing potential, and refusal to engage in proper safety evaluation and investigation, both before and after Depakote was first sold, were undertaken in the callous pursuit of market advantage and without regard for the safety of those exposed to Depakote, whether directly or in utero.

55. Therefore, in addition to their actual damages, Plaintiffs are entitled to recovery of exemplary damages against Abbott as a penalty or by way of punishment and to deter Abbott from similar conduct in the future.

COUNT IV

Breach of Implied Warranty

56. Plaintiffs incorporate the allegations contained in the foregoing paragraph as if fully set forth in the following paragraphs.

57. Abbott was a merchant seller with respect to Depakote.

58. In order to induce the purchase and/or use of Depakote, Abbott impliedly warranted to potential users of Depakote that it was safely tested and manufactured and was safe for the uses for which it was designed and/or advertised to be used.

59. Abbott breached this warranty in that Depakote was not safe for the uses for which it was manufactured and/or advertised.

60. Plaintiffs were injured as a result of detrimental reliance upon Abbott's implied warranties.

61. As a direct and proximate result of one or more of the foregoing breaches of implied warranty, Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

COUNT V

Breach of Express Warranty

62. Plaintiffs incorporate the allegations contained in the foregoing paragraph as if fully set forth in the following paragraphs.

63. Abbott was a merchant and seller with respect to Depakote.

64. In order to induce the purchase and/or use of Depakote, Abbott expressly warranted to potential users of Depakote that it was safely tested and manufactured and was safe for the uses for which it was designed and/or advertised to be used. Express warranties were contained in direct to consumer advertising and other promotional and marketing campaigns, Depakote product information sheets given to patients with their prescriptions, and other public communications and representations.

65. Abbott breached said warranty in that Depakote was not safe to be used for the purposes for which it was manufactured and/or advertised.

66. Plaintiffs were injured as a result of detrimental reliance upon Abbott's express warranties.

67. As a direct and proximate result of one or more of the foregoing breaches of express warranty, Plaintiffs suffered injuries and damages as described, in excess of $75,000.00.

COUNT VI

Intentional Infliction of Emotional Distress

68. Plaintiffs incorporate the allegations contained in the foregoing paragraph as if fully set forth in the following paragraphs.

69. Abbott's intentional, reckless and extreme conduct foreclosed any opportunity to adequately measure the level of risk related to Abbott's Depakote product. By withholding information of known design and manufacturing defects and concealing those fatal problems, Abbott created a false sense of security regarding the safety of Abbott's Depakote product.

70. Abbott's conduct of intentional omission, concealment, and failure to warn of the design and manufacturing defects caused Plaintiffs to suffer injuries, harm and economic loss as alleged herein, including permanent and substantial injuries, and expenses attributable to Abbott's conduct.

71. The injuries described above entitle Plaintiffs to compensatory damages in excess of $75,000.00 and equitable declaratory relief, along with all appropriate other damages according to proof.

COUNT VII

Negligent Infliction of Emotional Distress

72. Plaintiffs incorporate the allegations contained in the foregoing paragraph as if fully set forth in the following paragraphs.

73. Abbott intentionally and willfully failed to disclose or warn of the inherent risks and defects of Depakote, while knowingly concealing design, manufacturing and safety defects, and misrepresenting the risks of severe side effects, quality, safety, and efficacy of the durg.

74. Abbott's willful conduct inflicted Plaintiffs with severe emotional distress.

75. Abbott's conduct of willful omission and concealment of design, manufacturing and safety defects in order to induce ingestion of the drug caused Plaintiffs severe emotional distress.

76. As a direct result of Abbott's careless and negligent conduct, Plaintiffs have suffered and will continue to suffer injury, harm and economic loss as alleged herein, including permanent and substantial injuries, and expenses attributable to their injuries.

77. The injuries described above entitle Plaintiffs to compensatory damages in excess of $75,000.00 and equitable and declaratory relief, along with all other appropriate damages according to proof.

DAMAGES

78. Plaintiffs incorporate the allegations contained in the foregoing paragraph as if fully set forth in the following paragraphs.

79. The facts set out above demonstrate that, as a direct and proximate result of Abbott's conduct, Plaintiffs have suffered economic and non-economic losses and injuries for which they are entitled to recover damages in excess of $75,000.00, including without limitation the following:

(a) bodily injury, disfigurement, conscious pain, suffering, mental anguish, mental suffering, embarrassment, shame, loss of enjoyment of life, shortened life expectancy, loss of association, loss of earnings, loss of profits, loss of salary;

(b) the reasonable and necessary expenses for the medical treatment rendered to Plaintiffs in the past and that will be medically probable in the future;

(c) compensation for Plaintiffs permanent mental and physical impairment;

(d) all other actual damages available under applicable law;

(e) future economic damages during the age of minority and beyond the age of 18, including lost wages of Plaintiffs;

(f) costs of this suit.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that Defendant Abbott Laboratories, Inc. be cited to appear and answer herein. That upon final trial, Plaintiffs have judgment against Defendant Abbott Laboratories, Inc. in excess of this Court's jurisdictional requisite for actual damages, costs of the court, and any other relief that will fairly and adequately compensate for the losses herein alleged.

/s/ Christopher Cueto
Christopher Cueto, IL 06192248
Attorney for the Plaintiffs
Law Office of Christopher Cueto, Ltd.
7110 West Main
Belleville, IL 62223
Phone: 618-277-1554
Fax: 618-277-0962
CCueto@cuetolaw.com

Josh J. Wright
Attorney for the Plaintiffs
HOLLIS, WRIGHT, CLAY & VAIL P.C.
2201 Morris Avenue
Birmingham, Alabama 35203
T: (205) 324-3600
F: (205) 324-3636
joshw@hollis-wright.com